



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

November 5, 2019

Timothy M. Formella
Senior Product Registration Manager
FMC Corporation
2929 Walnut Street
Philadelphia, PA 19104

Subject: Pesticide Registration Improvement Act (PRIA) Labeling Amendment – To Remove the Expiration Date, Add an Alternate Brand Name, and Make Other Changes, Including Those Requested by the EPA (e.g., Update the CFR Citation in the Engineering Controls Section)
Response to the Storage Stability and Corrosion Characteristics Term of Registration
Product Name: F4018-4
EPA Registration Number: 279-3618
Application Date: June 19, 2019
OPP Decision Number: 552867

Dear Mr. Formella:

The amended labeling referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable.

The alternate brand name Avodigen Biological Fungicide/Nematicide has been added to the registration, and our records have been updated accordingly. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

A stamped copy of your labeling is enclosed for your records. This labeling supersedes all previously accepted labeling. You must submit one (1) copy of the final printed labeling before you release this product for shipment with the new labeling. In accordance with 40 CFR § 152.130(c), you may distribute or sell this product under the previously approved labeling for 18 months from the date of this letter. After 18 months, you may only distribute or sell this product if it bears this new revised labeling or subsequently approved labeling. "To distribute or sell" is defined under FIFRA section 2(gg) and its implementing regulation at 40 § CFR 152.3.

Should you wish to add/retain a reference to your company's website on your label, then please be aware that the website becomes labeling under FIFRA and is subject to review by the U.S. Environmental Protection Agency (EPA). If the website is false or misleading, the product will be

considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product's label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains statements or claims substantially differing from statements or claims made in connection with obtaining a FIFRA section 3 registration, the website will be referred to the EPA's Office of Enforcement and Compliance Assurance.

Your release for shipment of this product constitutes acceptance of these terms. If these terms are not complied with, this registration will be subject to cancellation in accordance with FIFRA section 6.

Additionally, in a memorandum dated October 16, 2019 (see one of the enclosures), the EPA rated submitted storage stability and corrosion characteristics data (MRID No. 508801-01) as supplemental but adequate to satisfy the term of registration. Thus, you have fulfilled term #2 of the May 17, 2018, F4018-4 Registration Notice.

If you have any questions, please contact Joseph Mabon of my team by phone at (703) 347-0177 or via email at mabon.joseph@epa.gov.

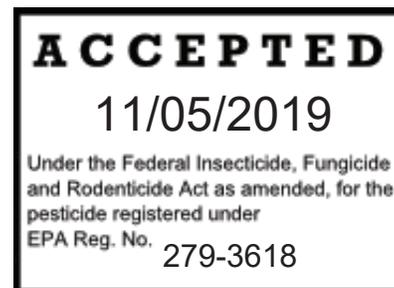
Sincerely,

A handwritten signature in black ink, appearing to read 'Jeannine Kausch', with a stylized flourish at the end.

Jeannine Kausch, Product Manager 92
Microbial Pesticides Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosures

F4018-4



[ABN: Avodigen™ Biological Fungicide/Nematicide]
[ABN: Avoda]

A biological fungicide/nematicide for seed treatment use for early season protection against listed fungal diseases and soil nematodes.

EPA Reg. No. 279-3618

EPA Est. No.

ACTIVE INGREDIENTS:	By Wt.
<i>Bacillus licheniformis</i> strain FMCH001*	3.50%
<i>Bacillus subtilis</i> strain FMCH002**	4.00%
OTHER INGREDIENTS:	92.50%
	100.00%

*Contains a minimum of 2.3×10^{10} colony-forming units (cfu) per milliliter of product.

**Contains a minimum of 2.3×10^{10} colony-forming units (cfu) per milliliter of product.

This product contains a total of 0.73 pound of active ingredients per gallon.

KEEP OUT OF REACH OF CHILDREN

See other panels for additional precautionary information.

Net Contents:

Sold By:
FMC Corporation
2929 Walnut Street
Philadelphia, PA 19104

Batch/Lot code: _____
[For nonrefillable containers only. Will be located on
this label or on the physical container.]

PRECAUTIONARY STATEMENTS

Personal Protective Equipment (PPE)

Applicators and other handlers (except treated seed baggers and bag sewers) must wear:

- long-sleeved shirt
- long pants
- waterproof gloves
- shoes plus socks
- A NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)

Treated seed baggers and bag sewers must wear:

- long-sleeved shirt
- long pants
- shoes plus socks
- A NIOSH-approved particulate respirator with any N, R, or P filter with NIOSH approval number prefix TC-84A; or a NIOSH-approved powered air purifying respirator with an HE filter with NIOSH approval number prefix TC-21C. (Repeated exposure to high concentrations of microbial proteins can cause allergic sensitization.)

User Safety Requirements

Follow manufacturer's instructions for cleaning/maintaining PPE. If no such instructions for washables exist, use detergent and hot water. Keep and wash PPE separately from other laundry.

Engineering Controls

When handlers use closed systems in a manner that meets the requirements listed in the Worker Protection Standard (WPS) for agricultural pesticides [40 CFR 170.607(d)], the handler PPE requirements may be reduced or modified as specified in the WPS.

IMPORTANT: When reduced PPE is worn because a closed system is being used, handlers must be provided all PPE specified above for "applicators and other handlers" and have such PPE immediately available for use in an emergency, such as a spill or equipment breakdown.

User Safety Recommendations

Users should:

- Wash hands before eating, drinking, chewing gum, using tobacco or using the toilet.
- Remove clothing/PPE immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing.
- Remove clothing/PPE immediately after handling this product. Wash the outside of gloves before removing. As soon as possible, wash thoroughly and change into clean clothing.

Environmental Hazards

For container sizes <5 gallons

For terrestrial uses: Do not apply directly to water, or to areas where surface water is present or to intertidal areas below the mean high water mark. Do not contaminate water when disposing of equipment washwater or rinsate.

For container sizes ≥5 gallons

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or other waters unless in accordance with the requirements of a National Pollutant Discharge Elimination System (NPDES) permit and the permitting authority has been notified in writing prior to discharge. Do not discharge effluent containing this product to sewer systems without previously notifying the local sewage treatment plant authority. For guidance, contact your State Water Board or Regional Office of the EPA.

DIRECTIONS FOR USE

It is a violation of Federal law to use this product in a manner inconsistent with its labeling.

Read entire label before using this product.

Do not apply this product in a way that will contact workers or other persons, either directly or through drift. Only protected handlers may be in the area during application. For any requirements specific to your State or Tribe, consult the State or Tribal agency responsible for pesticide regulation.

Agricultural Use Requirements

Use this product only in accordance with its labeling and with the Worker Protection Standard, 40 CFR Part 170. This standard contains requirements for the protection of agricultural workers on farms, forests, nurseries, and greenhouses, and handlers of agricultural pesticides. It contains requirements for training, decontamination, notification, and emergency assistance. It also contains specific instructions and exceptions pertaining to the statements on this label about personal protective equipment (PPE) and restricted-entry interval. The requirements in this box only apply to uses of this product that are covered by the Worker Protection Standard.

Do not enter or allow worker entry into treated areas during the restricted-entry interval (REI) of 4 hours.

Exception: If the product is soil injected or soil incorporated, the Worker Protection Standard, under certain conditions, allows workers to enter the treated area if there will be no contact with anything that has been treated.

PPE required for early entry to treated areas (that is permitted under the Worker Protection Standard and that involves contact with anything that has been treated, such as plants, soil or water) is:

- Coveralls
- Waterproof gloves
- Shoes plus socks

Non-Agricultural Use Requirements

The requirements in this box apply to uses that are NOT within the scope of the Worker Protection Standard (WPS) for agricultural pesticides (40 CFR Part 170). The WPS applies when this product is used to produce agricultural plants on farms, forests, nurseries, or greenhouses.

Keep unprotected persons out of treatment area until seeds have dried or been packaged.

Product Information

F4018-4 is a soluble seed treatment formulation that provides early season protection of seedlings against *Rhizoctonia* and *Fusarium* spp. in a variety of crops as well as suppression of root-knot nematode in corn and soybeans and soybean cyst nematode in soybeans. Seed must be sound and well-cured before treatment.

Seed Treatment Equipment

F4018-4 may be used both for commercial and for on-farm application. F4018-4 can be applied with mechanical, slurry, or mist-type seed treating equipment, as long as the equipment can be calibrated to accurately and uniformly apply the product to seed without undue mechanical damage to the seed. Uniform application to seed is important for all seed treatment products.

Application Instructions

Seed must be sound and well-cured before treatment. Refer to the application rates below. F4018-4 is diluted with chlorine-free water and/or mixed with other products to attain an appropriate slurry application volume (fl oz/cwt slurry rates) to provide effective treatment. Mix F4018-4 (application rates below) with a sufficient quantity of chlorine-free water and/or other products to attain a final targeted slurry rate of at least 4 fl oz/cwt. of seed on large seed crops such as corn and soybeans. On smaller size seeds such as grass or canola, a final targeted slurry rate of at least 8 fl oz/cwt. of seed is necessary to ensure adequate and uniform coverage. The appropriate volume of slurry depends on crop, temperature, humidity, type of treater, and other factors and must be adjusted per normal treating practices for the circumstances. Contact your local supplier or distributor representative for additional specifications for slurry volumes and questions on any tank mixes or restrictions.

F4018-4 plus chlorine-free water and/or other products must be mixed thoroughly prior to treating seed. Recalibrate treating equipment to compensate for the required slurry rate to ensure all products are applied at the correct application rate.

NOTE: This product does not contain dye and is not covered by an appropriate tolerance, tolerance exemption, or other clearance under the Federal Food, Drug and Cosmetic Act. To comply with 40 CFR 153.155(a), therefore, all seed treated commercially with this product must be colored with an EPA-approved dye or colorant of a suitable color to prevent accidental use as food for humans or feed for animals.

Do not use F4018-4 in combination with other seed treatment products unless compatibility has been verified. Read and follow carefully all label directions of each product used in the treating mixture. When using combinations of products, the most restrictive of label limitations and precautions must be followed.

Seed may be treated either on a per unit of seed basis or on a per weight of seed basis, as shown in the table below.

Crops, Pests and Application Rates

CROP	EARLY SEASON PROTECTION OF SEEDLINGS AGAINST INJURY FROM	APPLICATION RATE (Product/Seed Unit or Seed Weight)
Corn Field corn, Popcorn, Sweet corn, and Corn Grown for Seed	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp. and <i>Fusarium</i> spp. Root-knot nematode (suppression)	<u>Per Seed Unit:</u> 0.3 to 0.5 fl oz/80,000 seeds
Beans and Peas <i>Lupinus</i> spp., <i>Phaseolus</i> spp., <i>Vigna</i> spp., and <i>Pisum</i> spp.	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp. and <i>Fusarium</i> spp.	<u>Per Seed Weight:</u> 0.6 to 1.13 fl oz/cwt
Soybean	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp. and <i>Fusarium</i> spp. Root-knot nematode (suppression) Soybean cyst nematode (suppression)	<u>Per Seed Unit:</u> 0.51 to 0.75 fl oz/140,000 seeds
Fruiting Vegetables African Eggplant, Bell Pepper, Bush Tomato, Cocona, Currant Tomato, Eggplant, Garden Huckleberry, Goji Berry, Groundcherry, Martynia, Naranjilla, Nonbell Pepper, Okra, Pea Eggplant, Pepino, Roselle, Scarlet Eggplant, Sunberry, Tomatillo and Tomato (Cultivars, Varieties and/or Hybrids of these)	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 3.5 to 13.9 fl oz/cwt
Cucurbit Vegetables Chayote (Fruit), Chinese Waxgourd (Chinese Preserving Melon), Citron Melon, Cucumber, Edible Gourd (such as Chinese Okra, Cucuzza, Hechima, and Hyotan), Gherkin, <i>Momordica</i> spp. (such as Balsam Apple, Balsam Pear,	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 3.5 to 13.9 fl oz/cwt

Bitter Melon and Chinese Cucumber), Muskmelon (such as Cantaloupe), Pumpkin, Summer and Winter Squash (such as Acorn Squash, Butternut Squash, Calabaza, Crookneck Squash, Hubbard Squash, Scallop Squash, Spaghetti Squash, and Zucchini), and Watermelon		
Cereal Grains (except Corn) Barley, Buckwheat, Oats, Pearl and Proso Millet, Rice, Rye, Teosinte, Triticale, and Wheat	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 0.3 to 0.6 fl oz/cwt
Canola	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 3.5 to 13.8 fl oz/cwt
Cottonseed	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Unit:</u> 0.38 fl oz/100,000 seeds
Alfalfa, Forage, and Turf Grasses	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 1.4 to 13.8 fl oz/cwt
Root and Tuber Vegetables (except Potato and Sugarbeet) Arracacha, Arrowroot, Bitter and Sweet Cassava, Black and Spanish Salsify, Carrot, Celeriac (Celery Root), Chayote (Root), Chicory, Chinese and Jerusalem Artichoke, Chufa, Dasheen (Taro), Edible Burdock, Edible Canna, Garden Beet, Horseradish, Leren, Oriental Radish, Parsnip, Radish, Rutabaga, Salsify (Oyster Plant), Skirret, Sweet Potato, Tanier (Cocoyam), True Yam, Turmeric, Turnip, Turnip-rooted Chervil, Turnip-rooted Parsley, and Yam Bean	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Weight:</u> 3.5 to 13.9 fl oz/cwt
Sunflower	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Unit:</u> 0.38 fl oz/100,000 seeds
Sugarbeet	Seed rot and seedling blight caused by <i>Rhizoctonia</i> spp.	<u>Per Seed Unit:</u> 0.19 to 0.38 fl oz/100,000 seeds

Seed Bag Label Requirements

The Federal Seed Act requires that bags containing seed treated with this product shall be labeled with the following information:

- This seed has been treated with *Bacillus licheniformis* strain FMCH001 and *Bacillus subtilis* strain FMCH002.
- Do not use for food, feed or oil purposes. Store away from feed and food stuffs.

User is responsible for ensuring that the seed bag meets all requirements under the Federal Seed Act.

Use Restrictions

Do not use treated seed for food, feed or oil purposes. For at-planting seed treatments, treat only those seeds needed for immediate use, minimizing the interval between treatment and planting. Care must be exercised in the handling of treated seed. Augers used for handling treated seed must not be used to move seed for feed, food or oil processing. Do not reuse bags from treated seed to handle food or feed products.

STORAGE AND DISPOSAL

Do not contaminate water, food or feed by storage or disposal.

Pesticide Storage

Do not freeze. Do not store below 40° F. Shake or roll container to redissolve solids after storage and before use. Keep out of reach of children and animals. Store in original container only. Store in a cool, dry place and avoid excess heat. Carefully open container. After partial use, replace lid of container and close tightly. Do not put concentrate or dilute material into food or drink containers. Do not contaminate other pesticides, fertilizers, water, food, or feed by storage or disposal. In case of spill, avoid contact, isolate area, and keep out animals and unprotected persons. Confine spills. Call CHEMTREC (Transportation and Spills) at 1-800-424-9300. To confine spill, dike surrounding area or absorb with sand, cat litter or commercial clay. Place damaged package in a holding container. If a leaky container must be contained within another, mark the outer container to identify the contents.

Pesticide Disposal

To avoid wastes, use all material in this container by application according to label directions. If wastes cannot be avoided, offer remaining product to a waste disposal facility or pesticide disposal program (often such programs are run by state or local governments or by industry).

Container Handling

Nonrefillable Plastic Containers (Containers equal to or less than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank, and drain for 10 seconds after the flow begins to drip. Add water – at least 2% of the container volume, and up to $\frac{1}{3}$ of the volume of water needed to make the proper slurry composition with a maximum of $\frac{1}{4}$ of the container volume, and recap. Shake for 30 seconds. Pour rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Drain for 10 seconds after the flow begins to drip. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water. Then offer container for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill or by incineration.

Nonrefillable Plastic Containers (Containers greater than 5 gallons): Nonrefillable container. Do not reuse or refill this container. Triple rinse container (or equivalent) promptly after emptying. Triple rinse as follows: Empty the remaining contents into application equipment or a mix tank. Add water – at least 2% of the container volume, and up to $\frac{1}{3}$ of the volume of water needed to make the proper slurry composition with a maximum of $\frac{1}{4}$ of the container volume. Replace and tighten closures. Tip container on its side and roll it back and forth, ensuring at least one complete revolution, for 60 seconds. Stand the container on its end and tip it back and forth several times. Turn the container over onto its other end and tip it back and forth several times. Empty rinsate into application equipment or a mix tank, or store rinsate for later use or disposal. Repeat this procedure two more times. If used in application equipment, adjust the slurry volume application rate to account for any added rinsate water. Then offer container for recycling, if available, or reconditioning, if appropriate, or puncture and dispose of in a sanitary landfill or by incineration.

Conditions of Sale and Limitation of Warranty and Liability

Notice: Read the entire Directions for Use and Conditions of Sale and Limitation of Warranty and Liability before buying or using this product. If the terms are not acceptable, return the product at once, unopened, and the purchase price will be refunded.

The Directions for Use of this product must be followed carefully. It is impossible to eliminate all risks inherently associated with the use of this product. Crop injury, ineffectiveness, or other unintended consequences may result because of such factors as manner of use or application, weather or crop conditions beyond the control of FMC or Seller. All such risks shall be assumed by Buyer and User, and, to the extent consistent with applicable law, Buyer and User agree to hold FMC and Seller harmless for any claims relating to such factors.

Seller warrants that this product conforms to the compositional description on the label and is reasonably fit for the purposes stated in the Directions for Use when used in accordance with the directions under normal conditions of use.

TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, FMC MAKES NO WARRANTIES OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURPOSE, NOR ANY OTHER EXPRESS OR IMPLIED WARRANTIES WITH RESPECT TO THE SELECTION, PURCHASE, OR USE OF THIS PRODUCT. Any warranties, express or implied, having been made are inapplicable if this product has been used contrary to label instructions, or under abnormal conditions, or under conditions not reasonably foreseeable to (or beyond the control of) Seller or FMC, and, to the extent consistent with applicable law, Buyer assumes the risk of any such use.

Treatment of seed, especially seed that is mechanically damaged or seed known to be of low vigor and poor quality, may result in reduced germination and/or reduction of seed and seedling vigor. Treat and conduct germination tests on a small test sample of seed before treating commercial quantities with a selected treatment that includes this product. Due to seed quality and seed storage conditions beyond the control of FMC, FMC makes no claims or guarantees as to germination of carry-over seed.

To the extent consistent with applicable law, FMC or Seller shall not be liable for any incidental, consequential or special damages resulting from the use or handling of this product. TO THE EXTENT CONSISTENT WITH APPLICABLE LAW, THE EXCLUSIVE REMEDY OF THE USER OR BUYER, AND THE EXCLUSIVE LIABILITY OF FMC AND SELLER FOR ANY AND ALL CLAIMS, LOSSES, INJURIES OR DAMAGES (INCLUDING CLAIMS BASED ON BREACH OF WARRANTY, CONTRACT, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE) RESULTING FROM THE USE OR HANDLING OF THIS PRODUCT, SHALL BE THE RETURN OF THE PURCHASE PRICE OF THE PRODUCT OR, AT THE ELECTION OF FMC OR SELLER, THE REPLACEMENT OF THE PRODUCT.

This Conditions of Sale and Limitation of Warranty and Liability may not be amended by any oral or written agreement.

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